Congress of the United States
Washington, DC 20515

December 5, 2019

The Honorable Joseph J. Simons
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington DC 20580

The Honorable ADM Brett Giroir
The Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20994

Dear Chairman Simons and Acting Commissioner Giroir:

I am writing regarding the legal impediments that delay the release of generic and biosimilar pharmaceutical products to the market. When Americans rely on a wide range of medications for their health, it is vital that Congress gives the availability and affordability of these medications the attention they deserve. This effort involves working with your agencies to identify legal issues and find solutions that will lighten the financial burden of purchasing medication for families across the country.

I want to bring to your attention a Wall Street Journal article published on November 19, 2019, titled "Generic-Drug Approvals Soar, But Patients Still Go Without."[i] The article states:

> "Since 2016, the Food and Drug Administration has approved 2,492 generic versions of 617 brand-name drugs, according to health-data firm Iqvia. The approvals picked up after the agency began its effort in 2017 to address popular outrage with high drug prices by speeding the review of generic-drug applications.
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> The number of generic approvals has set records each of the past three fiscal years, according to the Trump administration. Officials have touted the efforts, saying that by bringing competition to the market, drug costs would fall. Generic competition reduces the price of branded drugs by an average of 39% of any branded drug with four copycats, according to an FDA analysis.
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> But less than two-thirds of generic drugs approved between 2016 and 2018, or 1,249 of the copies, were launched into the market, according to Iqvia. Through June, just 30%—or 134—of the 442 approvals this year have gone on sale. Roughly 40% of last year's 689 approvals haven't been launched. (The approvals may include more than one generic for the same molecule.)
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> The breakdown is especially acute for the most expensive medicines, so-called biologic drugs for ailments such as cancer and rheumatoid arthritis that often list for hundreds of thousands of dollars a year. Copies of these drugs, known as biosimilars, are also being

launched less frequently. Only 11 products are available commercially, despite more than two dozen approvals since 2015, the Journal's review found."

I am troubled by these findings and would like to better understand the barriers preventing generic drugs from entering the market and reaching patients. The article highlights certain defensive lawsuits pursued by brand-name patent-holders. Clearly, such lawsuits impede the entrance of affordable generic drugs into the market. Brand-name patent-holders have filed new patents for aspects of their products and have sued generic-drug companies for alleged patent infringement.

The article describes other reasons manufacturers of generics might struggle to start production, reading:

> "generic drugmakers deciding the potential return isn't as lucrative as initially thought. Sometimes their plants aren't ready to make the drugs, either. Meanwhile, consolidation among generic drugmakers has sharply cut the number of companies willing to sell the copies. The biggest factors, many of the generic-drug experts say, are the legal defenses mounted by brand-name drugmakers. They have sought to keep generics away by adding patents to products, while suing generic drugmakers for allegedly infringing the patents."

Congress will potentially act on anti-competitive practices like patent gaming this year to help more generics come to market. Given the respective roles your agencies play in this process, I would appreciate your perspectives on other legal impediments – statutory or regulatory – that keep generics from the market and that Congress might solve with legislation.

Please inform my office of any proposed legislative solutions or additional authorities your agencies may need to make lower-cost alternative products more available on the market. I look forward to working together to ensure Americans have access to affordable pharmaceuticals.

You may contact my Legislative Director, Chad Yelinski (chad.yelinski@mail.house.gov), with your response or if you have any questions.

Sincerely,

Mark R. Meadows
Member of Congress

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[i] "Generic-Drug Approvals Soar, But Patients Still Go Without," Wall Street Journal, Jared S. Hopkins, (November 19, 2019) https://www.wsj.com/amp/articles/many-generic-drugs-havent-hit-market-hindering-cost-control-efforts-11574198448.